

Remarks

Claims 1-6 are pending in the subject application. Applicants acknowledge that claims 3-6 have been withdrawn from further consideration as being drawn to a non-elected invention. By this Amendment, Applicants have canceled claims 1-6 and added claims 7-31. Support for the amendments and new claims can be found throughout the subject specification (see, for example, the originally filed claims and Examples 1-3 and 7 of the as-filed application). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 7-31 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

By this Amendment, Applicants have replaced the acronym “API” with “active pharmaceutical ingredient” in accordance with the Examiner’s suggestion. In addition, the acronym “API” and “PXR” have been inserted in parenthesis in claims 7 and 8, and the specification has been amended. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

Applicants also wish to bring to the Examiner’s attention application serial number 10/541,216, filed June 29, 2005. This application is currently pending and no Office Action has issued in that matter as of the date this response was filed.

Claims 1 and 2 are provisionally rejected for obviousness-type double patenting over claims 73-78 of co-pending application 10/551,014. Applicants respectfully assert that the claims as amended herein are not obvious over the claims of the cited application and that only claims 73 and 78 should have been used in this rejection. However, should the Examiner indicate allowable subject matter in the application, Applicants would consider filing a terminal disclaimer to address this rejection. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claim 2 is rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Applicants respectfully assert that the claim as filed is definite. While Applicants respectfully submit that the claim clearly indicates that the elements of claim 2 were recited in the alternative; however as the claim has been canceled, this issue is now moot. Applicants note that the newly presented claims recite each element in the alternative. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, as nonenabled by the subject

specification. The Office Action argues that undue experimentation would be required to identify “all active pharmaceutical ingredients” within the scope of the claim (relating to propylene glycol solvates of various APIs). Applicants respectfully assert that the claims are enabled by the subject specification. As the Patent Office is aware, enablement is a legal determination of whether a patent enables one skilled in the art to make and use the claimed invention (*Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983)) and is not precluded even if some experimentation is necessary. *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 U.S.P.Q. 409, 413 (Fed. Cir. 1984); *W.L. Gore and Associates v. Garlock, Inc.*, 721 F.2d 1540, 1556, 220 U.S.P.Q. 303, 315 (Fed. Cir. 1983). Applicants also submit that nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. However, in the interest of advancing prosecution in this matter, Applicants have canceled claims 1-2 and respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Salem *et al.* (1996). The Office Action indicates that the reference teaches polymorphic solvates of an API (terfenadine) in propylene glycol. Applicants respectfully assert that the Salem *et al.* reference does not anticipate the claimed invention as solvates of terfenadine are not encompassed by the current claims. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

Claims 1 and 2 are rejected under 35 U.S.C. § 103(a) as obvious over Bunnell *et al.* (U.S. Patent No. 5,736,541) in view of Kaplan *et al.* (U.S. Patent No. 3,970,651). The Office Action argues that the claimed solvates are obvious over the combined teachings of Bunnell *et al.* and Kaplan *et al.*, teaching the formation of olanzapine and propylene glycol for the formation of polymorphs of cephalosporin. Applicants respectfully assert that the claimed invention is not obvious over the cited references, regardless of whether the references are taken alone or in combination.

Obviousness requires a teaching that all elements of the claimed invention are found in the prior art and “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does” *KSR Int’l Co. v. Teleflex Inc.*, 127

S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007). Additionally, “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739, 82 USPQ2d 1385, 1395 (2007). However, Applicants respectfully submit that there is no fact-based reasoned analysis or evidence that would lead a person of ordinary skill in this art to conclude that the claimed propylene glycol solvates would be formed. As discussed in *KSR*, 127 S. Ct. at 1742, 82 USPQ2d at 1397, emphasis added, “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, **predictable** solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try **might** show that it was obvious under § 103.”

However, it is respectfully submitted that the formation of novel crystalline forms of various drugs is not predictable. For example, the Office Action argues that the formation of crystal structures is unpredictable, that the properties of any crystals formed for a given active pharmaceutical ingredient are unpredictable and that there was well accepted skepticism in the field of crystallography regarding the formation of crystal structures that were solvates of propylene glycol (see Office Action at page 9, citing to Gavezzotti, *Acc. Chem. Res.*, 1994, 27:309-314 and Rubino *et al.*, Reference R1 on the Information Disclosure Statement filed July 28, 2004). Accordingly, it is respectfully submitted that the claimed invention is not obvious over the combination of references as the Office Action fails to demonstrate that there is a “reasonable expectation of success” in arriving at the claimed invention and that it is unpredictable as to whether the claimed crystalline structures would be formed. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

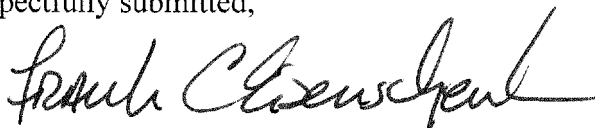
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants’ agreement with or acquiescence in the Examiner’s position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachment: Amendment Transmittal Letter